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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,302	03/12/2004	Jeffrey S. Kiel	455-030	8227
1009	7590	11/01/2006	EXAMINER	
KING & SCHICKLI, PLLC 247 NORTH BROADWAY LEXINGTON, KY 40507			SAMALA, JAGADISHWAR RAO	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/799,302

Applicant(s)

KIEL ET AL.

Examiner

Jagadishwar R. Samala

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/30/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Application Status

1. Applicant's response to the Office Action was acknowledged March 12, 2004

Claim Disposition

2. Claims 1-19 are pending and are under examination.

Information Disclosure Statement

3. The Information Disclosure Statement filed on July 30, 2004 has been received and entered the references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office Action.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Gordziel (US 6,037,358 here after '358), Chopdekar et al., (US 5,663,415 here after '415), or Leflein et al., (US 6,417,206 here after '206).

Claims 1-19 are drawn a manufacturing process for the conversion and incorporation of a salt or free base of an active pharmaceutical ingredient into a therapeutic liquid or semi-solid dosage form.

The patent '358 discloses a pharmaceutical preparations containing phenylephrine and chlorpheniramine in the form of tannate complex having antitussive, sympathomimetic decongestant and antihistaminic properties superior to the use of either one of the tannate compounds alone (see column 2, lines 12-17). The patent '358 also discloses the preparation of composition for oral administration in the form of powders, capsules, elixirs, syrups, suspensions and preferred forms of tablets containing the unique tannate salt combination in a conventional manner by the addition of suitable pharmaceutical carriers including fillers, diluents, lubricants and the like as well as conventional and well known binding and disintegrating agents (see column 2, lines 18-65 and column 3, example 2). Additionally for a typically process for the preparations of Pyrilamine tannate and phenylephrine tannate compositions (see US 3,197,370, US 5,599,846 and US 6,287,597). The teaching of the patent '358 possesses all the steps required as recited in claims. Thus, all the claims are anticipated.

The patent '415 discloses the preparation of pure antihistamine tannate compositions by a synthetic route which results in the production of compositions for dosage form to be administered either in solid form, i.e., pill or as a suspension, without further purification (see column 2, lines 1-45+). The patent '415 also discloses the preparation of tannat complexes of various antihistamines like phenylephrine, carbetapentane, pyrilamine, chlorpheniramine, ephedrine, pseudoephedrine, brompheniramine, diphenhydramine, pheniramine, phenyltolamine, clemastine,

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tripelennamine, phenindamine and phenyltoloxamine (see column 3, lines 1-7). The teaching of the patent '415 possesses all the steps required as recited in claims. Thus, all the claims are anticipated.

The patent '206 discloses tannate compositions consisting essentially of carbetapentane tannate, pyrilamine tannate and phenylephrine tannate which are effective when administered orally for the symptomatic relief of cough associated with respiratory tract conditions such as the common cold, bronchial asthma, acute and chronic bronchitis (see abstract).). The patent '206 also discloses the preparation of composition for oral administration in the form of powders, capsules, elixirs, syrups, suspensions and preferred forms of tablets containing the unique tannate salt combination in a conventional manner by the addition of suitable pharmaceutical carriers including fillers, diluents, lubricants and the like as well as conventional and well known binding and disintegrating agents (see column 2, lines 27-49). The patent '206 also discloses a conventional tableting procedure (see column 3 examples 1 and 2, where a suitable quantity of acid or base solution may be varied depending on the pH of the medium used in the batch. Tannic acid may also be used in lieu of sodium hydroxide solution for pH adjustment. Sodium Citrate, USP, Dihydrate and Citric Acid, USP, Anhydrous may also be included in the formula for pH adjustment). The teaching of the patent '206 possesses all the steps required as recited in claims. Thus, all the claims are anticipated.

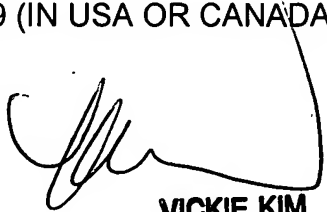
Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


VICKIE KIM
PRIMARY EXAMINER

Jagadishwar R Samala
Examiner
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